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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,064	04/27/2000	Ruth Elinor Bauhahn	11738.86893	2481
22908	7590	10/20/2005	EXAMINER	
BANNER & WITCOFF, LTD. TEN SOUTH WACKER DRIVE SUITE 3000 CHICAGO, IL 60606			BOCKELMAN, MARK	
			ART UNIT	PAPER NUMBER
			3766	

DATE MAILED: 10/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/560,064	BAUHahn ET AL.	
	Examiner	Art Unit	
	Mark W. Bockelman	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-9 and 40-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7-9 and 40-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9 is rejected under 35 U.S.C. 102(b) as being anticipated by WO/03218 to Fischell.

Fischell teaches an implantable pump and an external control device for programming the implantable device by accessing preset programs by the patient. The device allows various subroutines to be executed or not executed by selecting various prescription drug delivery profiles, basal rates etc. and allows these subroutines to be linked and thus create a personalized program so they will be stored as a personalized program and executed during use. The various prescriptions (namely insulin dosage) may be based upon patient activity (page 3 line 28). With regard to claim 4, the examiner considers the program to be “communicated” to the medical device when it is created in linking the subroutines. Amplitudes such as dosage level/basal level may be set and done so with drug delivery bolus (i.e. pulses) with delivery times (pulse width) and pulse frequency and a directional sequence (i.e. delivery times). Applicant's statements of intended use of claims 47 - 49 are given little patentable weight. The Fischell device is capable of delivering drugs, which would include including neurotransmitters and thus the device is capable of acting as a neuro stimulator. With

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regard to claim 45, the electrically activated pump requires electrode contacts as inputs to operate the pump. Electrode polarity being correct is necessary for operating the pump when activated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 7-9, 40-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snell USPN 5,456,691 in view of Fischell WO/03218 or vice versa. As pointed out in the previous office actions Snell teaches each of the limitations of claims 1, 9 and 40 with the exception that the patient does the programming of the device. To have allowed the patient to fine tune the drug delivery programs of Snell using a controller of Snell would have been obvious. Alternatively to have used the programmer of Snell for linking subroutines, wherein the subroutines are called up by a controller, modified and then down loaded would have been an obvious alternative for linking the subroutines.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark W. Bockelman whose telephone number is (571) 272-4941. The examiner can normally be reached on Monday - Friday 10:00 to 6:30.

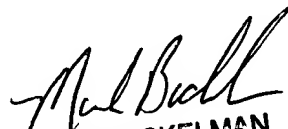
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272 -6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MWB

October 17, 2005


MARK BOCKELMAN
PRIMARY EXAMINER